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NUCLEAR WASTE MANAGEMENT PROGRAM PROCEDURE

NP 3-1 DESIGN CONTROL Revision 2

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	(printed name)	(signature)	date

1.0 Purpose and Scope

This procedure describes the process the Sandia National Laboratories (SNL) Nuclear Waste Management Program (NWMP) will use to ensure that conceptual through final designs are defined, controlled, and verified. This procedure is applicable to the design of engineered systems, structures, or components of the repository system which have a role in assuring that waste isolation performance objectives are achieved (e.g., shaft sealing systems). This procedure does not apply to the design of scientific investigation equipment set-ups, software, or computer systems used for analysis. See attached Flowchart for individual responsibilities in Appendix D.

Acronyms and definitions for terms used in this procedure may be found in the NWMP Glossary located at the SNL NWMP On-line Documents web site.

2.0 Implementation Actions

2.1 Design Planning Process

2.1.1 Design Plan Preparation

The key to developing a correct design product is to ensure that a detailed Design Plan (DP) has been prepared. This document will assist in documenting the complete design process from the selection of design inputs all the way through to the design verification and subsequent final release. The DP shall meet the content requirements described in Appendix A.

2.1.2 Design Verification Planning

The Principal Investigator (PI) will define the appropriate process to use for the design verification in this section of the DP. This phase of the design cycle will be performed by the members of a Technical Panel to ensure adequacy and compliance to the specified criteria for the design. The verification process for this panel is further described in Appendix A. The method and extent of the verification required shall be based on the complexity, risk, uniqueness of the design, complexity of design, degree of standardization, state of the art, and similarity with previously proven designs.

2.1.3 Design Plan Review and Approval

The cognizant Department Manager, Technical Reviewer, and the SNL QA staff member shall review and approve the DP in accordance with NP 6-1. In cases where the plan is used on a design project that involves organizations outside of SNL, the document will also be approved by the lead individuals from that organization.

2.1.4 Changes to Design Plans

Any revisions to the DP will follow the process specified in above and in NP 6-1 for the review and approval of the new document. The author shall ensure that revisions to the Design Plan are clearly indicated with vertical change bars in the margin of the revised Plan. (Note: Change bars will indicate changes for the current revision only.)

2.1.5 Design Plan Issuance

The PI shall submit the final DP to Document Control for issuance as a controlled document in accordance with NP 6-2. The DP should be made available to all design participants.

2.2 Performance of Design Analysis

When a PI determines that design analyses are needed on the project, they shall be planned, controlled, and documented to the extent necessary to produce the elements listed in Appendix B of this procedure. Any calculations performed on the design shall follow the steps in the appropriate procedure (e.g. NP 9-1) for documenting the calculations used. The design documentation shall provide enough detail for a technically qualified individual to understand and verify their adequacy without recourse to the originator. When software is used to conduct the analysis, the PI will ensure that NP 19-1 is followed.

2.3 Design Verification Process

The acceptability of design work and documents, including design inputs, processes, outputs, and changes, shall be verified at appropriate times during the design process. The following design control requirements shall be applied to verify the adequacy of design:

- A. Design verification shall be identified, justified, performed, and documented in accordance with project specific requirements based on one or both of the following methods, as determined by the Principal Investigator:
 - 1. design review
 - 2. alternate calculations

- B. The design verification shall be completed and approved before the design is released. A sample checklist for the verification is provided in Appendix C.
- C. Design verification shall be performed by competent individuals or groups other than those who performed the original design (but they may be from the same organization). If necessary, this design verification may be performed by the originator's supervisor provided that:
 - 1. the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design, or
 - 2. the supervisor is the only individual in the organization competent to perform the verification, and
 - 3. the determination to use the supervisor is documented and approved in advance by the QA Manager.
- D. Use of previously proven designs shall be controlled and documented to the same extent used for information developed for the DP. The applicability of standardized or previously proven designs shall be verified with respect to meeting pertinent design inputs for each application. Known problems encountered on standard or previous designs shall be evaluated with respect to the new application. The original design and associated verification measures shall be adequately documented and referenced in the files of the subsequent application. Lastly, any changes made to the previous design shall also be reverified before they are used on the new design.

2.4 Design Change

Design changes shall be controlled in accordance with the following requirements:

- A. changes to final designs, field changes, and nonconforming items dispositioned "use as is" or "repair" shall be justified and shall be subject to design control measures commensurate with those applied to the original design;
- B. design control measures for changes shall include provisions to ensure that the design analyses for the item are still valid;
- C. changes shall be approved by the SNL PI or organizations that reviewed and approved the original design documents;
 - 1. If an organization that originally was responsible for approving a particular design document is no longer responsible, then a new responsible organization shall be designated.
 - 2. The cognizant design organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.
- D. if a significant design change becomes necessary because of an incorrect original design, the design process and design verification methods and implementing procedures shall be reviewed and modified as appropriate. Deficiencies shall be documented according to the requirements provided in NP 16-1
- E. field changes shall be incorporated into the applicable design documents; and

- F. design changes that impact related implementing procedures or training programs shall be communicated to the affected organizations in accordance with NP 2-1.

3.0 Records

The following QA records, generated through implementation of this procedure, shall prepared and submitted to the NWMP Records Center in accordance with NP 17-1 (Records).

<u>QA Record</u>	<u>Preparer</u>	<u>Records Submitter</u>
• Design Plan documentation (Reference Appendix A)	Principal Investigator	Document Control
• Design development documents (Reference Appendix B)	Principal Investigator and support staff	Principal Investigator
• Document Review and Comment sheets (Form NP 6-1-1)	Reviewers	Principal Investigator

4.0 Appendices

- Appendix A: Design Plan Content
Appendix B: Design Documentation
Appendix C: Design Verification Checklist
Appendix D: Design Process Flowchart

Appendix A

Design Plan Content

The following information shall be included in Design Plans, as applicable:

1. Cover Page with title of the design, project name, effective date, Design Plan identifier, the name, date, and signature of the author (or authors), reviewers, and the individual approving the DP.
2. Design Inputs;
 - Objective of the design activity, the major components of the design, and the upper tier requirements or criteria that the engineered item or system must meet, and
 - Clearly describe the methods and assumptions used, and
 - Identification of design inputs and their sources. These shall be clearly identified with documented approval prior to beginning the design development.
3. Design Approach;
 - A summary of the tasks for the performing the design, the identification of participants assigned to complete them, and their estimated schedules,
 - Key interface organizations shall be identified with their responsibilities for the review, approval, release, distribution, and revision of documents. Design information transmitted across interfaces shall be documented, controlled, and identified with status,
 - The applicable standards that will be used on the design, such as ASTM, IEEE, or other,
 - The identification of any software to be used.
4. Design Verification;
 - A technical panel will be selected to conduct the design review or the evaluation of alternate calculations.
 - The verification method based on the requirements of Section 2.3 of this NP.
 - The identification of the technical review panel members and their areas of expertise, the QA reviewer, and the safety reviewer. In addition, one member of the technical review panel shall be designated as the Chairperson. This SNL staff member will facilitate the design review activity and assemble all completed documentation from the comment and resolution process.
 - The necessary training for the review team shall be clearly identified. Members of the review panel shall also document their qualifications in accordance with NP 2-1.
 - The plan shall also provide guidance for conducting the review to include the schedule for the review, using NP 6-1 documentation, and the comment resolution process.
 - The design review criteria which meet the appropriate upper tier requirements.

Appendix B

Design Documentation

Design record packages shall provide sufficient documentation so that a technically qualified person could understand the work and verify its adequacy without recourse to the originator. The following information shall be included in a completed design package, as applicable;

1. The Design Plan (DP) and any revisions.
2. List of names and roles of individuals who participated in developing and reviewing the design.
3. The identification of any computer software and platform used in performing the design analyses. Reference the procedures used to qualify the codes, such as NP 9-1 or NP 19-1.
4. Representation of the work performed and results obtained;
 - Tables, plots, and discussion of results sufficient to demonstrate to an equally qualified technical person that the results of the design adequately meet the purpose of the analyses.
 - Results of literature searches or other applicable background data.
 - Discussions of any other items that are necessary for traceability and reproducibility.
5. Documentation of any changes from the design plan or inputs that occurred during the performance of the design and the reasons for the changes if not covered above (not required if the plan is revised and re-issued).
6. Documentation of the review for the design work, which is further discussed in NP 6-1.
7. Design output documents (specification, drawings, etc...), including review documentation. These documents shall contain appropriate inspection and testing acceptance criteria. Where necessary, complete designs that require further evaluation, review, or approval shall be identified.

Appendix C

Design Verification Sample Checklist

Design verification shall be performed and documented using one or both of the following checklists		
Method	Yes/No?	
I. Design Review		
<p>A. Design reviews shall be controlled, documented, and performed. Design reviews shall consider the following:</p> <ol style="list-style-type: none"> 1. design inputs were correctly selected and incorporated; 2. assumptions necessary to perform the design work were adequately described, reasonable, and reverified as necessary; 3. appropriate design methods were used; 4. design output is reasonable compared to design inputs; and 5. the necessary design input and verification requirements for interfacing organizations were specified in the design documents or in supporting implementing procedures. <p>B. Disposition of design review comments shall be documented in accordance with the requirements of NP 6-1.</p>		
II. Alternate Calculations		
<p>These are calculations or analyses that are made using alternate methods to verify correctness of the original calculations or analyses. The appropriateness of any assumptions, the input data used, any computer programs, or other calculation methods used shall be evaluated and documented in accordance with Appendix B of NP 3-1.</p> <p>These calculations or analyses shall meet the requirements of NP 9-1, as appropriate.</p>		
Verifier: <div style="display: flex; justify-content: space-between; margin-top: 20px;"> <div style="width: 30%; border-top: 1px solid black; text-align: center;">Print Name</div> <div style="width: 30%; border-top: 1px solid black; text-align: center;">Signature</div> <div style="width: 30%; border-top: 1px solid black; text-align: center;">Date</div> </div>		

Appendix D

Design Process Flow Chart

